SUMMARY OF:

P070008/S36, P950037/S116, P050023/S58, P000009/S51

Ilesto 7 / 5 VR-T ICD, Ilesto 7 / 5 VR-T DX ICD, Ilesto 7 / 5 DR-T ICD, Ilesto 7 / 5 HF-T CRT-D; Iforia 7 / 5 VR-T ICD, Iforia 7 / 5 VR-T DX ICD, Iforia 7 / 5 DR-T ICD, Iforia 7 / 5 HF-T CRT-D; and the PSW 1205.U

Biotronik, Inc.
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BACKGROUND/REASON FOR SUPPLEMENT

The 180-day PMA/S (subject file) was submitted by Biotronik (the company) for requesting the approval of the above referenced ICD/CRT-D, the programmer application software, and the CardioMessenger. The subject device is the improvement (upgrade) from the previously approved ICDs/CRT-Ds. The following is a summary of the differences:

Hardware changes (housing and header changes, electronic module design change, updated feedthroughs, batteries and HV capacitors)

New features (Atrial Capture Control, Biventricular Asynchronous Pacing Modes, Remote Scheduling of remote periodic follow-ups)

Updated firmware for CardioMessenger II and CardioMessenger II-S patient devices to support Remote Scheduling

Updated (b) (4) programmer software version to support Ilesto 7/5 and Iforia 7/5 devices

INDICATIONS FOR USE:

ICDs:

The Ileso/Iforia Family of Implantable Cardioverter Defibrillators (ICDs) is intended to provide ventricular antitachycardia pacing and ventricular defibrillation, for automated treatment of lifethreatening ventricular arrhythmias.

The Ilesto/Iforia VR-T DX ICDs are part of a system that includes both the Kainox A+ and the Ilesto/Iforia VR-T DX ICD devices.

CRT-Ds:

Indications for Use: The Ilesto/Iforia CRT Ds are indicated for use in patients with all of the following conditions:

- Indicated for ICD therapy
- Receiving optimized and stable Congestive Heart Failure (CHF) drug therapy
- Symptomatic CHF (NYHA Class III/IV and LVEF ≤ 35%)
- Intraventricular conduction delay (QRS duration ≥ 130 ms)

DEVICE DESCRIPTIONS

The company claims the subject device (the Ilesto and Iforia families of ICD/CRT-D devices) is based on the company's current legally marketed Lumax 740 ICD/CRT-D device families with the primary modifications related to hardware and final devices sizes. From a functional/ available feature standpoint, the Ilesto and Iforia devices are nearly identical to the Lumax 740 family. Significant hardware modifications were made to the following:

Electronic Module construction and orientation (electrical schematic is nearly identical)

Battery – improvements implemented

HV Capacitors – improvements implemented

Feedthroughs and Telemetry Coil – Modifications implemented to ease manufacturing

Titanium housing – reduced size

In addition, there were minor changes to create a new version (PSW 1205.U) of programmer software as compared to the currently legally marketed version (PSW 1203.U/1). The primary reason for modification of the programmer software was to implement the following software based features:

Atrial Capture Control

Enabling Remote Scheduling of Home Monitoring Periodic Follow-ups

Biventricular Asynchronous Pacing Modes

Finally, this PMA Supplement includes minor changes to the firmware for BIOTRONIK's current legallymarketed Home Monitoring "patient devices" called the CardioMessenger II and CardioMessenger II-S families of devices.

Notes:

(b) (4) [redacted]

[redacted].

THE SUMMARY FOR THE REVIEW

The subject implantable device contains the new features and those new features were reviewed by the FDA clinician, to make sure those new features are acceptable without the clinical data. Based on the clinical review, those new features are acceptable for the subject implantable device.

The subject implantable device is required to be tested for all the modifications, (b) (4) [redacted], risk analysis, test plans, etc. are required to be part of the submittal.

Based on the above, the following are the summary of the information in the subject file.

(b) (4) [redacted]

(b) (4) [redacted]

The Differences between Ilesto/Iforia 7 and Ilesto/Iforia 5 are:

Reduction in the amount of information available for an atrial diagnostic feature in the **Ilesto/Iforia** 5 family. The Ilesto/Iforia 5 family only has the ability to record the pre-history of atrial episodes (AT/AF events) for approximately 30 seconds, while the Ilesto/Iforia 7 family can record this atrial prehistory for >1 minute. This information is provided in the labeling, therefore, it is acceptable.

The longevity regardless of battery used for Ilesto/Iforia 5 (b) (4) [redacted] is reduced compared to Ilesto/Iforia 7 (b) (4) [redacted]). The company (b) (4) [redacted], therefore, this is acceptable.

There are no other differences between the Ilesto/Iforia 7 and Ilesto/Iforia 5 device families.

BIOCOMPATIBILITY: N/A

ANIMAL STUDY: N/A

CLINICAL DATA: N/A

LABELING:

The final drafted labeling for the subject device is provided in the file, one the major modifications is the device longevity with respect to the battery types.

CONCLUSION

It is recommended to send the 'Approval' letter to the company, based on the information in the file, e-mails, and conference calls..